UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ELIZABETH K. BROWN **PLAINTIFF**

v. **Case No. 1:09-cv-01412-JFK**

MERCK & CO., INC. and SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE **DEFENDANTS**

AMENDED COMPLAINT

Plaintiff Elizabeth K. Brown ("Plaintiff"), by and through her attorneys, files her Amended Complaint against Defendant Merck & Co., Inc. and Smithkline Beecham Corporation d/b/a Glaxosmithkline ("Defendants"), and allege as follows:

I. PARTIES

1. Plaintiff, Elizabeth Brown, was born on March 2, 1925, and is an adult, resident citizen of the city of Wildwood, Sumter County, State of Florida. Plaintiff used Fosamax from approximately March of 2000 to March of 2008.

2. At all times herein mentioned, Merck & Co., Inc. was and is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889-0100.

3. At all times herein mentioned, Smithkline Beecham Corporation, d/b/a Glaxosmithkline was and is a corporation organized and existing under the laws of the State of Pennsylvania, with its principal place of business at One Franklin Plaza, Philadelphia, Pennsylvania 19101.

4. At all times herein mentioned, Defendants were authorized to conduct business in the States of New York, New Jersey and Florida.

5. Defendants have regularly transacted business in the State of Florida and continue to do so.

6. At all relevant times Merck & Co. Inc., through its agents, servants, employees and apparent agents was the designer, manufacturer, marketer, distributor and seller of Fosamax, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis, osteopenia, and Paget's Disease.

7. At all relevant times Smithkline Beecham Corporation, d/b/a Glaxosmithkline, through its agents, servants, employees and apparent agents was the designer, manufacturer, marketer, distributor and seller of Boniva, a bisphosphonate drug used primarily to manage postmenopausal osteoporosis, maintain bone density and reverse bone loss.

8. Defendant, Merck & Co., Inc., both directly or through its agents, apparent agents, servants or employees, at all relevant times, sold and distributed Fosamax in the State of Florida.

9. Defendant, Smithkline Beecham Corporation, d/b/a Glaxosmithkline, both directly or through its agents, apparent agents, servants or employees, at all relevant times, sold and distributed Boniva in the State of Florida.

10. Defendants derive substantial revenue from pharmaceutical products used or consumed in the State of Florida.

11. Defendants expected, or should have expected, that its business activities could or would have consequences within the State of Florida.

II. JURISDICTION AND VENUE

12. This Court has original jurisdiction over this action under 28 U.S.C. § 1332, in that the amount in controversy exceeds seventy-five thousand dollars ($75,000.00) and Plaintiff is a citizen of a State which is different from the State where the Defendants are incorporated and has its principal place of business, such that complete diversity of the parties exists.

13. Venue is proper under 28 U.S.C. § 1391(a) because a significant portion of the material events giving rise to this action occurred in Sumter County, Florida, where Plaintiff is a resident.

III. FACTUAL BACKGROUND

14. Defendants, either directly or through its agents, apparent agents, servants or employees, at all relevant times, designed, tested, developed, manufactured, labeled, marketed, distributed and sold Fosamax and Boniva.

15. Plaintiff, Elizabeth Brown, was prescribed and ingested the prescription drug, Fosamax, from March 2000 to February 2006 and also from April 2007 to November 2007, and was prescribed and ingested the prescription drug, Boniva, from February 2006 to April 2007 and also from November 2007 to December 2007. On or about December 2007, Plaintiff was diagnosed with Osteonecrosis of the Jaw.

16. In September 1995, the United States Food and Drug Administration ("FDA") approved Defendant's compound alendronate for various uses, including the treatment of osteoporosis and Paget's Disease. Alendronate is marketed by Defendant as Fosamax.

17. Fosamax is the brand name of alendronate sodium, which is in a class of prescription drugs called bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's disease. Other drugs within this class, such as Aredia and Zometa, are used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis. Fosamax is taken orally.

18. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia); ibandronate (Bondronate); and alendronate (Fosamax). The non-nitrogenous bisphonsphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate contains a

nitrogen atom. The Physicians Desk Reference ("PDR") for Fosamax confirms that the molecule contains a nitrogen atom.

19. Throughout the 1990s and 2000s, medical articles and studies appeared reporting the frequent and common occurrence of osteonecrosis of the jaw within the nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, Merck knew or should have known that Fosamax, as a nitrogenous bisphosphonates, shared a similar adverse event profile to the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).

20. Defendants knew or should have known that bisphosphonates, including Fosamax and Boniva, inhibit endothelial cell function. Similarly, Defendants knew or should have known that bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patients' mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.

21. Defendants also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can turn into a non-healing wound. This condition can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

22. Dentists are now being advised by dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on Fosamax.

23. Once the osteonecrosis begins and becomes symptomatic, it is very difficult to treat and typically is not reversible.

24. Shortly after Defendant began selling Fosamax, reports of osteonecrosis of the jaw and other dental complications among users began surfacing, indicating that Fosamax shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Defendant failed to implement further studies of risk of osteonecrosis of the jaw relative to

Fosamax. Rather than evaluating and verifying the safety of Fosamax with respect to osteonecrosis of the jaw, Defendant proposed further uses of Fosamax, such as Fosamax-D, and sought to extend the exclusivity period of Fosamax through 2018.

25. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.

26. Since Fosamax was released, the FDA has received a significant number of reports of osteonecrosis of the jaw among users of Fosamax and continues to do so.

27. On August 25, 2004, the United States Food and Drug Administration ("FDA") posted on it ODS Postmarking Safety Review on bisphosphonates - - specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (Actonel), and aledronate (Fosamax). This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.

28. As a result of the FDA review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that the osteonecrosis of the jaw was a class effect which specifically extended to the oral bisphosphonate Fosamax.

29. As a result, in January of 2005 the FDA recommended and stated that the labeling for Fosamax should be amended by Defendant to specifically warn about the risk of osteonecrosis of the jaw. Defendant hid this recommendation from physicians and did not make the requested change until July of 2005.

30. Fosamax is one of the Defendant's top selling drugs, averaging more than $3 billion a year in sales.

31. Defendants knew of the significant risk of dental and oral complications caused by ingestion of Fosamax and Boniva, but Defendants did not adequately and sufficiently warn consumers, including Plaintiff, or the medical community, of such risks.

32. As a direct result, Plaintiff was prescribed Fosamax and Boniva and has been permanently and severely injured, having suffered serious consequences from the ingestion of Fosamax and Boniva. Plaintiff now requires and will require in the future ongoing medical care and treatment.

33. Plaintiff has suffered from mental anguish from the knowledge that Plaintiff will have life-long complications as a result of the injuries Plaintiff sustained from the use of Fosamax and Boniva.

34. Plaintiff used Fosamax and Boniva as prescribed and in a foreseeable manner.

35. As a direct and proximate result of using Fosamax and Boniva, Plaintiff suffered severe osteonecrosis of the jaw.

36. Plaintiff, as a direct and proximate result of using Fosamax and Boniva, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.

37. Plaintiff would not have used Fosamax and/or Boniva had Defendants properly disclosed the risks associated with the drugs. Alternatively, Plaintiff would not have known the precursor events of osteonecrosis of the jaw and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.

38. Defendants, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with taking Fosamax and Boniva. The running of any applicable statue of limitations has been tolled by reason of Defendants' fraudulent concealment.

39. As a result of Defendants' actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

IV. COUNTS

COUNT I: STRICT LIABILITY

40. Plaintiff restates the allegations set forth above as if fully set forth herein.

41. Defendants manufactured, sold, distributed, marketed, and/or supplied Fosamax and Boniva in a defective and unreasonably dangerous condition to consumers, including Plaintiff.

42. Defendants designed, manufactured, sold, distributed, supplied, marketed, and/or promoted Fosamax and Boniva, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

43. Plaintiff used Fosamax and Boniva as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendant.

44. Fosamax and Boniva failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

45. Fosamax and Boniva were defective in its design and were unreasonably dangerous in that its risks exceeded the benefits associated with its design or formulation.

46. Fosamax and Boniva was defective in design or formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

47. Fosamax and Boniva was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor accompanied by warnings adequate to alert consumers, including Plaintiff, of the risks described herein, including, but not limited to, the risk of osteonecrosis of the jaw.

48. Although Defendants knew or should have known of the defective nature of Fosamax and Boniva, they continued to design, manufacture, market, and sell Fosamax and

Boniva so as to maximize sales and profits at the expense of the public health and safety. By so acting, Defendants acted with conscious and deliberate disregard of the foreseeable harm cause by Fosamax and Boniva.

49. Plaintiff could not, through the exercise of reasonable care, have discovered Fosamax's and Boniva's defects or perceived the dangers posed by the drug.

50. As a direct and proximate consequence of both Defendants' conduct, Plaintiff sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur medical and physical pain and suffering.

51. Defendants' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff hereby entitling Plaintiff to punitive damages, so as to punish Defendants and deter it from similar conduct in the future.

WHEREFORE, Plaintiff request judgment against Defendants for damages in excess of $75,000.00 together with costs, punitive damages, interest, and any further legal or equitable relief this Court deems appropriate.

COUNT II: NEGLIGENCE

52. Plaintiff restates the allegations set forth above as if fully set forth herein.

53. Defendants owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling Fosamax and Boniva.

54. Defendants failed to exercise due care under the circumstances and therefore breached this duty by:

a. failing to properly and thoroughly test Fosamax and Boniva before releasing the drug to market;

b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of Fosamax and Boniva;

c. failing to conduct sufficient post-marketing testing and surveillance of Fosamax and Boniva;

d. designing, manufacturing, marketing, advertising, distributing, and selling Fosamax and Boniva to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of Fosamax and Boniva and without proper instruction to avoid the harm which could occur as a result of using the drug;

e. failing to exercise due care when advertising and promoting Fosamax and Boniva; and

f. negligently continuing to manufacture, market, advertise, and distribute Fosamax and Boniva after Defendants knew or should have known of its adverse effects.

55. As a direct and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

56. Defendants' conduct as described above was committed with knowing, conscious, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

WHEREFORE, Plaintiff request judgment against Defendants for damages in excess of $75,000.00, together with costs, punitive damages, interest, and any further legal or equitable relief this Court deems appropriate.

COUNT III: NEGLIGENT MISREPRESENTATION

57. Plaintiff restates the allegations set forth above as if fully set forth herein.

58. Defendants made fraudulent misrepresentations with respect to Fosamax and Boniva in the following particulars:

a. Defendants represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Fosamax and Boniva has been tested and found to be safe and effective for the treatment of osteoporosis and other conditions; and

b. Defendants represented that Fosamax and Boniva was safer than other alternative medications.

59. Defendants knew that its representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of Fosamax and Boniva to consumers, including Plaintiff, and the medical community.

60. The representations were made by Defendants with the intent that doctors and patients, including Plaintiff, rely upon them.

61. Defendants' representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of Fosamax and Boniva.

62. Plaintiff's doctors and others relied upon the representations.

63. Defendants' fraudulent representations evinced it callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

64. As a direct and proximate result of the Defendants' actions, Plaintiff sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and cost include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

65. Defendants' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff hereby entitling Plaintiff to punitive damages, so as to punish Defendants and deter it from similar conduct in the future.

WHEREFORE, Plaintiff request judgment against Defendants for damages in excess of $75,000.00, together with costs, punitive damages, interest, and any further legal or equitable relief this Court deems appropriate.

COUNT IV: FRAUDULENT CONCEALMENT

66. Plaintiff restates the allegations set forth above as if fully set forth herein.

67. Defendants fraudulently concealed information with respect to Fosamax and Boniva including but not limited to the following particulars:

a. Defendants represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Fosamax and Boniva has been tested and found to be safe and effective for the treatment of osteoporosis and other conditions; and

b. Defendants represented that Fosamax and Boniva was safer than other alternative medications.

68. Defendants had sole access to material facts concerning the dangers and unreasonable risks of Fosamax and Boniva.

69. The concealment of information by Defendants about the risks of Fosamax and Boniva was intentional, and the representations made by Defendants were known by Defendants to be false.

70. The concealment of information and the misrepresentations about Fosamax and Boniva were made by Defendants with the intent that doctors and patients, including Plaintiff, rely upon them.

71. Plaintiff's doctors and others relied upon the representations and were aware of the substantial dental and oral risks of Fosamax and Boniva which Defendants concealed from Plaintiff's doctors and Plaintiff.

72. As a direct and proximate result of the Defendants' fraudulent concealment, Plaintiff sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and related services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and cost include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

73. Defendants' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff hereby entitling Plaintiff to punitive damages, so as to punish Defendants and deter it from similar conduct in the future.

WHEREFORE, Plaintiff request judgment against Defendants for damages in excess of $75,000.00, together with costs, punitive damages, interest, and any further legal or equitable relief this Court deems appropriate.

COUNT V: BREACH OF IMPLIED WARRANTY

74. Plaintiff restates the allegation set forth above as if fully set forth herein.

75. Defendants manufactured, distributed, advertised, promoted, and sold Fosamax and Boniva.

76. At all relevant times, Defendants knew of the use for which Fosamax and Boniva was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

77. Defendants were aware that consumers, including Plaintiff, would use Fosamax and Boniva for treatment of osteoporosis and for other purposes.

78. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Defendants to sell Fosamax and Boniva only if it was indeed of merchantable quality and safe and fit for its intended use.

79. Defendants breached its implied warranty to consumers, including Plaintiff; Fosamax and Boniva were not of merchantable quality or safe and fit for its intended use.

80. Consumers', including Plaintiff, and the medical community, reasonably relied upon Defendants' implied warranty for Fosamax and Boniva.

81. Fosamax and Boniva reached Plaintiff and other consumers without substantial change in the condition in which it was manufactured and sold by Defendants.

82. As a direct and proximate result of Defendants' actions, Plaintiff, sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and related services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of

preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and cost include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

83. Defendants' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff hereby entitling Plaintiff to punitive damages, so as to punish Defendants and deter it from similar conduct in the future.

WHEREFORE, Plaintiff request judgment against Defendants for damages in excess of $75,000.00, together with costs, punitive damages, interest, and any further legal or equitable relief this Court deems appropriate.

COUNT VI: BREACH OF EXPRESS WARRANTY

84. Plaintiff restates the allegations set forth above as if fully set forth herein.

85. Defendants expressly represented to Plaintiff and the medical community that Fosamax and Boniva was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.

86. Fosamax and Boniva does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.

87. At all relevant times, Fosamax and Boniva did not perform as safely as an ordinarily consumer would expect, when used as intended or in a reasonably foreseeable manner.

88. Plaintiff, other consumers, and the medical community relied upon Defendants' expressed warranties.

89. As a direct and proximate result of the Defendants' actions, Plaintiff sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare

services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and cost include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

90. Defendants' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff hereby entitling Plaintiff to punitive damages, so as to punish Defendants and deter it from similar conduct in the future.

WHEREFORE, Plaintiff request judgment against Defendants for damages in excess of $75,000.00, together with costs, punitive damages, interest, and any further legal or equitable relief this Court deems appropriate.

V. DAMAGES

91. Plaintiff restates the allegations set forth above as if fully set forth herein.

92. The negligent and/or grossly negligent acts, breaches, omissions, misrepresentations, concealment and other wrongful conduct by the Defendants proximately caused significant injury to the Plaintiff. As a direct and proximate result of the aforesaid negligent and/or grossly negligent acts, breaches, omissions, misrepresentations, concealment and other wrongful conduct, Plaintiff, Elizabeth K. Brown, sustained osteonecrosis of the jaw.

WHEREFORE, Plaintiff request judgment against Defendants for damages in excess of $75,000.00, together with costs, punitive damages, interest, and any further legal or equitable relief this Court deems appropriate.

VI: PRAYER FOR RELIEF

93. THEREFORE, the above premises considered, Plaintiff demands a trial and judgment of and from the Defendants, for actual, compensatory, and punitive damages within the jurisdictional limits of this Court plus legal interest from the date of filing this Complaint, all costs of this Court, and all other relief that Plaintiff may be entitled to at equity or at law, including but not limited to compelling Defendants to adequately warn about the risk of osteonecrosis of the jaw and Fosamax.

VII. DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and issues so triable.

DATED this 19th day of April, 2010.

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